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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/021,753

10/30/2001

Ken Fujise

UTSH:251US

6306

7590 10/09/2007
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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

MAIL DATE	DELIVERY MODE
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10/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/021,753

Applicant(s)

FUJISE ET AL.

Examiner

J. Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39, 40, 46, 47, 63-66, 68-83 and 88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39, 40, 63-66, 68-70, 73-83 and 88 is/are rejected.
- 7) ☒ Claim(s) 46, 47, 71 and 72 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Action is in response to the communication filed on 8/27/2007.

The amendment filed 8/27/2007 is acknowledged and has been entered.

Claims 39, 40, 46, 47, 63-66, 68-83 and 88 are currently pending in the application and are addressed herein.

Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 39, 40, 63-66, 68-70, 73-83, 88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification must adequate written description and evidence of possession of a claimed genus. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description'

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inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

The instant claims encompass methods which require assaying Fortilin polypeptide activity either in vitro or in a cell (e.g., see claims 39 and 68). Therefore, the claims encompass a genus of Fortilin activities wherein the genus encompasses all possible Fortilin activities. Thus the claims encompass a genus of Fortilin activities that is indeterminate in size, but could potentially encompass an enormous number of different activities, including Fortilin activities that have not yet been identified. Looking to the specification for the written description of the genus of Fortilin activities encompassed by the claims, it appears that the specification only provides describes Fortilin binding to p53 polypeptide and Fortilin binding to MCL1 polypeptide as the only activity of the Fortilin polypeptide which could be measured in the instant claims. The specification discloses that Fortilin is involved in prevention of apoptosis via p53 and MCL1 binding. The specification does not describe any other Fortilin activity encompassed by the genus of Fortilin activities in the claims, and none are found in the prior art. Therefore, the skilled artisan cannot envision any other Fortilin activity encompassed by the claims, and as such, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. In this case, the activity itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

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Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Therefore, the only Fortilin polypeptide activities encompassed by the claims which are adequately described in the specification are Fortilin-p53 binding and Fortilin-MCL1 binding.

3. Claims 39, 40, 63-66, 68-70, 73-83, 88 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods wherein the Fortilin activity is Fortilin-p53 binding and Fortilin-MCL1 binding, does not reasonably provide enablement for the full scope of the claimed methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

The invention is in a class of invention which the CAFC has characterized as “the unpredictable arts such as chemistry and biology.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

As indicated above, the claims encompass methods which require assaying Fortilin activity either in vitro or in a cell (e.g., see claims 39 and 68). As such, the claims encompass methods that require assaying a genus of Fortilin activities wherein the genus encompass all possible Fortilin activities, a genus of activities that could encompass an enormous number of different activities, including Fortilin activities that have not yet been identified.

The specification only describes Fortilin binding to p53 polypeptide and Fortilin binding to MCL1 polypeptide as the only activity of the Fortilin polypeptide which could be measured in the instant claims. The specification discloses that Fortilin is involved in prevention of apoptosis via p53 and MCL1 binding. The specification does not describe any other Fortilin activity encompassed by the genus of Fortilin activities in the claims, and none are found in the prior art. Therefore, additional experimentation would be required in order to practice the claimed methods to their full scope. That is, additional experimentation would be required in order to identify Fortilin the activities which could be assayed in the instantly claimed method, other than Fortilin-p53 binding and Fortilin-MCL1 binding. This additional experimentation amounts to trial-and-error testing of potential Fortilin activities without guarantee of success. Furthermore, the identification of any other Fortilin activity would amount to a significant and unobvious advance over the state of the art. Therefore, the additional amount of experimentation required to practice the claimed methods to their full scope is considered to be undue.

It is noted that amending the independent claims such that the Fortilin activities are limited to p53 binding and MCL1 binding would obviate these rejections.

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Claim Objections

4. Claims 46, 47, 71, 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner
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